Drug Use Investigation for Arzerra Chronic Lymphocytic Leukemia (CLL) (116789)

First published: 26/06/2015

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10093

Study ID

48996

DARWIN EU® study

No

Study countries

Japan

Study description

This investigation will be conducted to collect and evaluate information regarding the safety and efficacy of Arzerra under the actual post-marketing use conditions of the product.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 150 centres are involved in the study

Contact details

Study institution contact

Clinical Disclosure Officer Clinical Disclosure Officer

trialandresults.registries@novartis.com

Study contact

trialandresults.registries@novartis.com

Primary lead investigator

Clinical Disclosure Officer Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/12/2012

Actual: 25/12/2012

Study start date
Planned: 31/07/2013

Actual: 30/07/2013

Data analysis start date
Planned: 30/06/2022

Actual: 05/04/2022

Date of final study report
Planned: 15/11/2022

Actual: 14/06/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

gsk-116789-protocol-redact.pdf (109.66 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Other study registration identification numbers and links

COMB157A1401

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

This investigation will be conducted to collect and evaluate information regarding the safety and efficacy of Arzerra under the actual post-marketing use conditions of the product.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multicenter observational study

Study drug and medical condition

Medicinal product name

ARZERRA

Medical condition to be studied

Chronic lymphocytic leukaemia

Population studied

Short description of the study population

The study involved a multicenter observational investigation of Arzerra, a drug used to treat relapsed or refractory chronic lymphocytic leukemia. The target sample size was 300 patients, and data was obtained after administration under actual use conditions. A central registration system was adopted for patient enrollment.

Patients who received Arzerra for the indication of relapsed or refractory CD20-positive chronic lymphocytic leukemia were included in the study. Patients who started receiving Arzerra before the study contract concluded were also considered study patients.

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Special population of interest

Hepatic impaired

Immunocompromised

Other

Pregnant women

Renal impaired

Special population of interest, other

Patients with chronic lymphocytic leukemia

Estimated number of subjects

300

Study design details

Outcomes

Information regarding the safety and efficacy of Arzerra under the actual post-marketing use conditions of the product.

Data analysis plan

Items related to patient disposition, patient demographic and baseline characteristics, items related to safety, and items related to efficacy

Documents

Study results

ReExam-COMB157A1401-CSR-E_Redacted.pdf (1.57 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No